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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,101	01/21/2000	Ali O. Gure	L0461/7073(JRV)	5361

7590 12/10/2003

John R Van Amsterdam
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600 Atlantic Avenue
Boston, MA 02210

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

5. M.

Advisory Action

Application No.

09/489,101

Applicant(s)

GURE ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 17 November 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 1,2,121,123,125,126,128,130-132,134 and 135.

Claim(s) withdrawn from consideration: NONE.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Gary Benzion

Continuation of 5. does NOT place the application in condition for allowance because:

The claims have been amended to incorporate the limitations of dependant claims into the independent claim.

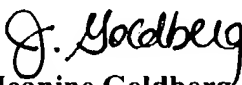
The response asserts that the SOX2 gene excludes brain, testis, prostate, small intestine and colon tissue (response filed November 17, 2003). The response further asserts that small cell lung cancer cell lines contain cell lines which were isolated from tissues other than primary lung cancer. However, based upon the specification, "SOX2 was expressed in 5/10 SCLC cell lines." The specification lists the cell lines. None of the cell lines in the table on page 6 of the response are among the cell lines listed in the list of cell lines which express SOX2. Therefore, it is unclear and unpredictable that SOX2 is expressed in tissues other than lung, as asserted by the instant response.

With respect to the 112/1st para rejection, ZINC2 gene expression was analyzed (Example 3, page 56). The response states that screening for the presence of the claimed sequences is typical and routine in clinical laboratories (page 7 of response filed November 17, 2003). This argument has been thoroughly reviewed, but is not found persuasive because while it is acknowledged that determining expression levels is typical and routine, the outcome of such experiments is unpredictable and undue. Claim 132, for example, is drawn to detecting breast, colon, head & neck cancers, but there is no indication that the products are not expressed in these tissues. It is unpredictable whether the ZINC2 is expressed in each of these tissues since there is no indication in the specification. Further since ZINC2 is expressed in some normal tissues, it is unpredictable whether the ZINC2 is expressed in any other of the claimed tissues. The response states that the issue of threshold is meaningless, because any detectable expression would be sufficient to be diagnostic of cancer. This argument has been thoroughly reviewed, but is not found persuasive because if the normal tissues also express the ZINC2 mRNA, without overexpression or underexpression at a significant level, the skilled artisan would be unable to diagnose the particular cancers. Thus, while the specification teaches the presence of ZINC2 in the claimed cancers, it is unpredictable whether they were also expressed in normal tissue. Therefore, the claims still require further undue experimentation to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
Patent Examiner
December 8, 2003